

Amendment and Response

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Serial No.: 10/640,853

Confirmation No.: 9178

Filed: August 13, 2003

For: ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND METHODS

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CENTRAL FAX CENTER****MAR 06 2007****Remarks**

The Office Action mailed December 6, 2006 has been received and reviewed. Claims 1-56, 62, 63, and 71-78 having been amended, the pending claims are claims 1-18 and 20-78. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejection

Claims 1, 3-9, 20, 22-27, 29-32, 34-61, 63-69, 71, 73, and 74-78 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 10/640,714 and claims 1-51 of copending Application No. 10/640,702. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-18 and 20-78 under 35 U.S.C. §102(b) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner has further rejected claims 1-18 and 20-78 under 35 U.S.C. §102(b) as being anticipated by Whitbourne et al. (U.S. Patent No. 6,110,483).

Of the rejected claims, claims 1, 10, 20, 32, 56, 63, and 75-78 are independent. Each of the independent claims has been amended to recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent. Each of the remaining claims depends, directly or indirectly, from one of the amended claims and, consequently, contains all of the language of the amended claims.

Hossainy et al. teaches polymer coated stents and processes for coating stents. Hossainy et al. teaches a variety of considerations that can be used to select polymers: tackiness, adherence, deformability, toughness, elasticity, melting point (col. 5, lines 39-51), and active

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agent release rate (col. 7, lines 18-55 and col. 9, lines 26-32). Hossainy et al. neither explicitly nor inherently teaches selecting polymers based on their miscibility.

The claims, as amended herein, recite methods in which the second polymer is selected to be miscible with the first polymer. This language specifically recites the exploitation of Applicants' discovery—namely, identifying and selecting polymers that are miscible to form a miscible polymer blend for controlling delivery of an active agent—by the skilled artisan practicing the claimed method. Thus, the claimed methods include the conscious selection of polymers based on miscibility. Methods in which miscible polymers are selected merely by happenstance are excluded. The present claims recite a cognitive and discretionary step that was unknown and, therefore, impossible prior to Applicants' disclosure. In the absence of evidence that one of the polymer selection criteria specified in Hossainy et al. *necessarily* results in selection of miscible polymers, Hossainy et al. cannot anticipate Applicants' amended claims.

Whitbourne et al. teaches medicated coatings that can include miscible polymer blends particularly suited for controlling the lubricity, stability, swelling, flexibility, adhesion, and resistance to removal by wet abrasion (col. 9, lines 29-32). Whitbourne et al. neither explicitly nor inherently teaches selecting miscible polymers particularly suited for controlling the release of an active agent.

The claims recite methods in which the second polymer is selected so that, when combined with the first polymer, the resulting miscible blend possesses the recited characteristics that define the blend as one capable of controlling release of an active agent. This language specifically recites the exploitation of Applicants' discovery—namely, identifying and selecting polymers that are miscible to form a miscible polymer blend for controlling delivery of an active agent—by the skilled artisan practicing the claimed method. Thus, the claimed methods include the conscious selection of polymers based on their ability to form a miscible blend capable of controlling the release of an active agent. Methods in which miscible polymer blends capable of controlling the release of an active agent are selected for other reasons are excluded. The present claims recite a cognitive and discretionary step that was unknown and, therefore, impossible prior to Applicants' disclosure. In the absence of evidence that the selection of miscible polymer blends under one of the criteria set forth in Whitbourne et al. *necessarily* results in the selection

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of miscible polymers that are capable of controlling release of an active agent, Whitbourne et al. cannot anticipate Applicants' amended claims.

Applicants submit that claims 1, 10, 20, 32, 56, 63, and 75-78 are patentable under 35 U.S.C. §102(b) over each of Hossainy et al. and Whitbourne et al. Each of the remaining claims depends, directly or indirectly, from one of the aforementioned independent claims and, therefore, is patentable for at least all of the reasons that its independent claim is patentable. Thus, Applicants submit that claims 1-18 and 20-78 are patentable under 35 U.S.C. §102(b) over each of Hossainy et al. and Whitbourne et al.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-18 and 20-78 under 35 U.S.C. § 103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner has further rejected claims 1-18 and 20-78 under 35 U.S.C. § 103(a) as being unpatentable over Whitbourne et al. (U.S. Patent No. 6,110,483).

As noted above, each of the independent claims has been amended to recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order form a miscible blend particularly suited for tunable delivery of an active agent.

Applicants submit that Hossainy et al. fails to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Hossainy et al. fails to set forth each and every element of the claims. The deficiencies of the teachings of Hossainy et al. are set forth above.

Applicants further submit that Whitbourne et al. fails to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Whitbourne et al. fails to set forth each and every element of the claims. The deficiencies of the teachings of Whitbourne et al. are set forth above.

Applicants submit that claims 1, 10, 20, 32, 56, 63, and 75-78 are patentable under 35 U.S.C. §103(a) over each of Hossainy et al. and Whitbourne et al. Each of the

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remaining claims depends, directly or indirectly, from one of the aforementioned independent claims and, therefore, is patentable for at least all of the reasons that its independent claim is patentable. Thus, Applicants submit that claims 1-18 and 20-78 are patentable under 35 U.S.C. §103(a) over each of Hossainy et al. and Whitbourne et al.

Summary

It is respectfully submitted that the pending claims 1-18 and 20-78 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 6 day of March, 2007, at 5:15pm (Central Time).

By: Deb Schurmann

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